



Australian Government

Department of Health

COMMONWEALTH OF AUSTRALIA

DEPARTMENT OF HEALTH

National Health Act 1953

National Health (Pharmaceutical Benefits) Regulations 2017

INSTRUMENT OF APPROVAL

I, THEA DANIEL, Assistant Secretary, Pricing and Pharmaceutical Benefits Scheme Policy Branch, Technology Assessment and Access Division, Department of Health, delegate for the Secretary of the Department of Health, acting under section 12 of the *National Health (Pharmaceutical Benefits) Regulations 2017* (the Regulations), approve the information technology requirements in this instrument for the following purposes:

- (a) preparing or submitting an electronic prescription;
- (b) giving information, for the purposes of the Regulations, in relation to an electronic prescription, an authorisation that relates to an electronic prescription or an electronic order form;
- (c) giving or presenting an electronic prescription to an approved supplier under the Regulations;
- (d) giving an acknowledgement under the Regulations for the supply of a pharmaceutical benefit under an electronic prescription or an authorisation that relates to an electronic prescription; and
- (e) doing any other thing that is required or permitted to be done for the purposes of the Regulations.

Dated this 29th day of October 2019.

(Signed by)

A handwritten signature in black ink that reads "Thea Daniel".

THEA DANIEL

Assistant Secretary

Pricing and Pharmaceutical Benefits Scheme Pricing Branch

Technology Assessment and Access Division

Delegate of the Secretary of the Department of Health

1 Name of Instrument

This instrument is the *Electronic Prescriptions Information Technology Requirements Instrument 2019*.

2 Commencement

This instrument commences on 31 October 2019.

3 Interpretation

In this instrument:

approved information technology requirements means the information technology requirements set out in this instrument for the purposes set out in section 4.

electronic prescription has the same meaning as in the *National Health (Pharmaceutical Benefits) Regulations 2017*.

healthcare provider organisation has the same meaning as in the *Healthcare Identifiers Act 2010*.

information technology requirements include software requirements, within the meaning given by subsection 5(1) of the *Electronic Transactions Act 1999*.

information means information in the form of data, text, images or speech.

information system means a system for generating, sending, receiving, storing or otherwise processing electronic communications.

Regulations means the *National Health (Pharmaceutical Benefits) Regulations 2017*.

4 Purpose

The purpose of this instrument is to approve information technology requirements for electronic prescriptions, within the meaning of section 12 of the Regulations, for the following purposes:

- (a) preparing or submitting an electronic prescription;
- (b) giving information, for the purposes of the Regulations, in relation to an electronic prescription, an authorisation that relates to an electronic prescription or an electronic order form;
- (c) giving or presenting an electronic prescription to an approved supplier under the Regulations; and
- (d) giving an acknowledgement under the Regulations for the supply of a pharmaceutical benefit under an electronic prescription or an authorisation that relates to an electronic prescription; and
- (e) doing any other thing that is required or permitted to be done for the purposes of the Regulations.

5 Information Technology Requirements

(1) Security system requirements

- (a) Information systems, used by healthcare provider organisations for the purpose of processing electronic prescriptions provided by users, must be in accordance with the *Electronic Prescriptions Security Policy* for security requirements relating to

concepts that include encryption and retention of data, secure messaging, identification of users and authorisation of access to systems.

- (b) Information systems that generate, send, receive, store or otherwise process an electronic prescription must have appropriate mechanisms for system security, such as procedures for control of access to and use of systems, establishing and maintaining system administrator permissions, managing retention and backup of data and ensuring passwords are confidential.

(2) Privacy implementation requirements

- (a) Information systems used by healthcare provider organisations must have mechanisms in place to allow users to adhere to the *Electronic Prescriptions Privacy Policy* that outlines obligations under the *Privacy Act 1988* relating to privacy of personal information when using electronic prescriptions.
- (b) Information systems must provide for the recording of consent by a patient or a third party on behalf of the patient, prior to provision of personal information to other systems used to support access to electronic prescription information.
- (c) Information systems must be capable of automatically generating a privacy notice relating to collection of personal information by the Australian Government for the assessment and administration of payments and services, in a form approved by the Chief Executive Medicare in accordance with the *Form of the Electronic Prescription 2019*.
- (d) Information systems that generate, send, receive, store or otherwise process an electronic prescription must have systems in place to allow users to adhere to organisational policies, and ensure personal information is managed appropriately within these systems to allow the safe and secure use of electronic prescriptions.

(3) Data Usage

Information systems used by healthcare provider organisations must ensure that prescription data is only accessed, stored, transmitted and used in accordance with the *Electronic Prescriptions Data Usage Policy*.

(4) Safety

Information systems used by healthcare provider organisations must allow users to take all reasonable steps to ensure the safety and integrity of electronic prescription data and personal information associated with the electronic prescription.

(5) Software Conformance

- (a) Information systems that provide for the preparation, transmission and dispensing of an electronic prescription must conform with the *Electronic Prescribing Conformance Scheme* maintained by the Australian Digital Health Agency to gain a valid conformance identifier.

- (b) A valid conformance identifier is required for inclusion in the metadata of the electronic prescription for each information system used to generate, send, receive, store or otherwise process the electronic prescription.

(6) *Accountability*

Information systems must provide accurate, detailed and complete record of all electronic prescription transactions processed, and healthcare provider organisations must produce these on demand as required under legislation.

(7) *Acknowledgement of Supply*

If a person is requested to write an acknowledgement in accordance with subsection 57(1) of the Regulations for the supply of a pharmaceutical benefit under an electronic prescription, or an authorisation that relates to an electronic prescription, the information system may allow acknowledgement to be taken to be met by the receipt of supply flag to be checked by an approved supplier when using the claims transmission system in relation the supply of that pharmaceutical benefit, in accordance with subsection 57(2)(a) of the Regulations.

(8) *Authentication*

- (a) Information systems must have in place a process for authentication by PBS prescribers in accordance with regulation 9 of the Regulations.
- (b) The authentication requirement to be taken to be met for an electronic prescription by allowing for submissions by an authenticated user (single-factor, multi-stage or multi-factor) with the proof of signing met by the system allowing for the capture of an audit trail against the electronic prescription.
- (c) Where authentication is single stage or multi-factor, additional authentication parameters (including password rules) must be provided for.
- (d) The system must enable the electronic prescription to be sent to a conformant information system along with user credentials and the healthcare provider identifiers of the organisation and of the individual (if any).
- (e) Information systems must ensure appropriate authentication requirements are in place that will allow the safe and secure use of an electronic prescription, and may be detailed in organisational privacy and security policies.
- (f) Information systems must establish authentication parameters as set out in the *Electronic Prescribing Conformance Profile*.